AUG 2 7 2001

K002328

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RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation:
Company / Institution name: **Richard Wolf Medical Instruments Corp.**			FDA establishment regulation number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913-1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913-0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP/Postal Code: 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:	
Trade name: SIOS compatible CAN Bus Interface for Auto Light Projector, 3 CCD Camera, Laparo CO_2 Pneu Insufflator	Model number: 5131.012 5507.752 2232.622
Common name: SIOS compatible CAN Bus Interface	Classification Name: Insufflator, Camera and Light Source for Endoscopy

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K944821/A	1 Light source, Xenon 5151	1 Richard Wolf
2 K952696	1 Light source, Xenon 5121	2 Richard Wolf
3 K92965	3 Endocam 5502/5507, CF insulation	3 Richard Wolf
4 K991906	4 Laparo CO_2 Insufflator 2232	4 Richard Wolf
5 pending	5 SIEMENS Integrated Operating System (SIOS)	5 Richard Wolf
6	6	6

1.0 Description

The light source AUTO-LP 5131, camera, 3 CCD ENDOCAM 5507, and the insufflator LAPARO CO_2-PNEU 2232 have additional interface for integrating into the SIOS system by Siemens for remote control and/or voice control.

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2.0 Intended Use

The devices have an additional **Can Bus interface** for integration into the "SIEMENS Integrated Operating System (SIOS)" for remote control and/or voice control of their functions.

Light Projector: The AUTO-LP 5131 light projector provides the necessary light for examination, diagnostic and therapeutic intervention in endoscopy.

Camera: The 3CCD ENDOCAM 5507 is designed for video endoscopy and video microscopy. It is intended for both diagnostic and therapeutic intervention.

Insufflator: The LAPARO CO_2-PNEU automatic insufflator generates and maintains pneumoperitoneum under CO_2 gas in diagnostic and operative laparoscopy.

3.0 Technological Characteristics

The devices have an additional SIOS compatible CAN Bus, operation via the push buttons at the front of the camera head.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as existing devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf.

5.0 Performance Data

The devices conform to the international standards UL-2601-1, IEC601-1, with A1 and A2, IEC601-1-1-1 with A1 , IEC606012-18 and IEC62D/191/FDIS.

The submitted devices conform to the relevant provisions of Medical Device Directive 93/42/EEC, and this is certified by a conformity assessment procedure according to Annex II and VIII.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness when used according to the instruction manual.

By: Robert L. Casarsa Date: July 27, 2000

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 7 2001

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corp.
353 Corporate Woods Parkway
VERNON HILLS IL 60061

Re: K002328
SIOS-Interface for Auto Light Projector (5131.012)
SIOS-Interface for 3 CCD Endocam (5507.752)
SIOS-Interface for Laparo CO_2 PNEU Insufflator (2232.622)
Dated: June 15, 2001
Received: June 18, 2001
Regulatory Class: II
21 CFR §884.1730/Procode: 85 HIF
21 CFR §876.1500/Procode: 78 GCT
21 CFR §878.4160/Procode: 78 FWF

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K002328

Device Name: Devices with SIOS compatible CAN Bus Interface

Intended Use:

The devices have an additional **CAN Bus interface** for integration into the "SIEMENS Integrated Operating Systems (SIOS) for remote control and/or voice control of their functions.

Insufflator:

The LAPARO CO_2-PNEU automatic insufflator generates and maintains pneumoperitoneum under CO_2 gas in diagnostic and operative laparoscopy.

Camera:

The 3 CCD ENDOCAM 5507 is designed for video endoscopy and video microscopy. It is intended for both diagnostic and therapeutic intervention.

Light Projector:

The AUTO-LP 5131 light projector provides the necessary light for examination, diagnostic and therapeutic applications in endoscopy.

Contraindications:

Contraindications for the patient resulting from the general findings and described in the relevant literature must be observed. Refer to current literature for further instructions.

Combinations:

The AUTO-LP 5131, 3 CCD ENDOCAM 5507, and LAPARO CO_2 -PNEU can be integrated by the use of the additional interfaces into the SIOS System by Siemens

Only the components, which are released for SIOS use, are allowed to be connected to the Interface "SIOS-BUS" .

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K002328

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter _____